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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,718	01/28/2002	Kenji Asano	0230-0161P	3333

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/856,718

### Applicant(s)

ASANO ET AL.

### Examiner

Susan D. Coe

### Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/7/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on July 7, 2004 has been entered.

2. Claims 1-10 and 12-20 are currently pending.

### ***Priority***

3. Applicant's acceptance for 371 status has been vacated as of the petition decision dated August 17, 2004. Thus, this application is not granted the 371 filing date of the PCT application. The filing date of this application is now considered to be the US filing date of January 28, 2002. Priority to the foreign applications, JP 10/353927 and JP 10/353928, cannot be granted because their filing dates were more than a year prior to January 28, 2002.

### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It was not executed in accordance with either 37 CFR 1.66 or 1.68.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Pat. Pub. No. 2000-159686.

JP '686 teaches a LAK activity enhancer obtained from *Lentinus edodes* (shiitake mushrooms). The mushrooms are made in the same manner as claimed. The mushrooms are first cultured on a medium with bagasse and defatted rice bran. Water and an enzyme is then added to the cultured mushrooms. The enzyme is selected from cellulase, protease, or glucosidase. The medium is then ground. The temperature is then raised to 95 degrees C to sterilize and deactivate the enzyme (see paragraph 16 of the English translation).

The LAK enhancer thus obtained is administered to treat cancer. The enhancer is administered to humans and animals in a variety of forms.

6. Claims 1-10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 7-173070.

US 2004/0038330 is the English equivalent of JP 7-173070; thus, it will be referred to in this rejection.

US '330 teaches an extract from shiitake mushroom. This process is described on page 2 and in claim 1. The extract is made by culturing the mushroom in a medium of bagasse and rice bran. Water and enzymes are then added to the culture containing medium. The enzyme is

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selected from cellulase, protease, and glucosidase. Then the medium is ground. The temperature is then raised to a temperature between 75 to 95 degrees C. The extracted mycelium can then be filtered.

The reference does not specifically teach that the shiitake extract is a LAK activity enhancer. However, since the reference product and the claimed product are made using the same process, the reference product would inherently contain all of the characteristics of the claimed product. If the reference product does not function in this manner, than the invention would not function as claimed.

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Susan D. Coe, Examiner  
September 15, 2004